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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,020	11/08/2000	Christoph Benning	MSU-04769	3130

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Peter G Carroll  
Medlen & Carroll LLP  
220 Montgomery Street  
Suite 2200  
San Francisco, CA 94104

EXAMINER

PAK, YONG D

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 11/26/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/709,020

Applicant(s)

BENNING ET AL.

Examiner

Yong Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 October 2001.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 13, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 13, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The amendment filed on October 9, 2001, canceling claims 2-12 and 14, amending claims 1 and 13 and adding claims 15-16, has been entered.

Claims 1, 13 and 15-16 are pending.

### ***Specification***

The sequences in Figure 3 should be identified by SEQ ID as previously stated in the Office action (Paper No. 4).

### ***Claim Rejections - 35 USC § 103***

Claims 1, 13 and newly submitted claims 15-16 are rejected under 35 U.S.C. 103(a) as being obvious over Essigmann et al. in view of Guler et al.

Essigmann et al. teach a polypeptide, plant SQD1, that catalyzes the formation of a UDP-sulfoquinovose from UDP-glucose to (page 31, 4<sup>th</sup> paragraph) and the SQD1 gene is 100% identical to SEQ ID NO:6 of the instant invention (GenEmbl database – Accession # AF022082). Essigmann et al. teach a method for transfecting a host cell with the said DNA to express the SQD1 enzyme (page 32, 5<sup>th</sup> paragraph). Essigmann et al. also teach that sulfite can be used as the sulfur donor (and page 40, 3<sup>rd</sup> paragraph). In addition, figure 1 of the Essigmann et al. reference outlines the pathway for the synthesis of a SQDG from UDP-glucose, a sulfur donor, DAG. Essigmann et al.

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also teach that SQDG of photosynthetic bacteria and plants are a promising anti-tumor and anti-HIV therapeutic (page 30, abstract).

The difference between the reference of Essigmann et al. and the instant invention is that the reference of Essigmann et al. does not teach a polypeptide that catalyzes the transfer of sulfoquinovose from UDP-sulfoquinovose onto diacylglycerol.

Guler et al. teach a polypeptide, SQDX from a cyanobacteria, that catalyzes the transfer of sulfoquinovose from UDP-sulfoquinovose onto diacylglycerol (page 545, 1<sup>st</sup> paragraph) and the *sqdX* gene is 100% identical to SEQ ID NO:1 of the instant invention (GenEmbl database – Accession #U45308). Essigmann et al. teach a method for transfecting a host cell with the said DNA to express the SQD1 enzyme (page 544, 2nd paragraph). Guler et al. teach that the *sqdX* gene product is essential for sulfolipid biosynthesis in cyanobacteria (page 545, 1<sup>st</sup> paragraph).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make a UDP-sulfoquinovose with the SQD1 of Essigmann et al. and SQDG from the UDP-sulfoquinovose with the SQDX of Guler et al. The motivation of using the *sqd1* and *sqdX* gene product is that the encoded enzymes can be used to produce SQDG instead of by chemical synthesis or isolation by standard biochemical methods in order obtain SQDG of high yield and purity. An efficient production of SQDG is attractive because sulfolipids are possible anti-tumor and anti-HIV therapeutics. One of ordinary skill in the art would have had a reasonable expectation of success since Essigmann et al outlines the pathway for SQDG

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production and production of a product using recombinant enzymes in lieu of chemical synthesis is routinely performed.

Rejection of claim 1 under 35 U.S.C. 112, first paragraph, has been withdrawn due to its amendment.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

***Response to Arguments***

Applicant's arguments filed October 9, 2001 have been fully considered but they are not persuasive.

Rejection of claims 1-2, 5 and 13-14 under 35 U.S.C. 102(b) as being anticipated by Essigmann et al. has been withdrawn due to amendment of claim 1.

Rejection of claims 1-2 and 4-5 under 35 U.S.C. 103(a) as being unpatentable over Essigmann et al. in view of Mulichak et al. has been withdrawn due to the amendment of claim 1 and cancellation of claims 4-5.

Claims 1 and 13 remain rejected under 35 U.S.C. 103(a) as being anticipated by Essigmann et al. in view of Guler et al.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by

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combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Essigmann et al outlines the pathway for SQDG synthesis in Figure 1, page 31, starting from UDP-glucose to UDP-sulfoquinovose to SQDG. Applicants argue that the Examiner admitted that Essigmann et al. do not teach how to make SQDG using various sulfur groups. This statement was made regarding the various sulfur donor groups listed on canceled claim 4. Essigmann et al. do teach that a sulfite can be used as the sulfur donor (page 40, 3<sup>rd</sup> paragraph and Office Action, Paper No. 4).

The motivation of using the *sqd1* and *sqdX* gene product is that the encoded enzymes can be used to produce SQDG instead of making SQDG by chemical synthesis or isolation by standard biochemical methods. The advantage of employing the two enzymes is to obtain SQDG of high yield and purity. An efficient production of SQDG is attractive because sulfolipids are possible anti-tumor and anti-HIV therapeutics.

Applicants also argue that the references do not disclose a reasonable expectation of success (Remarks, page 12). The Examiner disagrees. One of ordinary skill in the art would have had a reasonable expectation of success since Essigmann et al outlines the pathway for SQDG production and the two references teach which

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enzyme is necessary for the pathway. Also, production of compounds using recombinant enzymes in lieu of chemical synthesis is routinely performed.

Applicants also argue that even if the references are combined, the references do not teach all of the elements (Remarks, page 12). The examiner disagrees. As mentioned above, Essigmann et al. teach a pathway for the synthesis of SQDG, figure 1 on page 31. Essigmann et al. teach that SQD1 catalyzes formation of UDP-sulfoquinovose from UDP and a sulfur donor and Guler et al. teach that SQDX catalyzes the formation of SQDG from UDP-sulfoquinovose. As mentioned above, Essigmann et al. does teach that a sulfite can be used as the sulfur donor (page 40, 3<sup>rd</sup> paragraph). Since the enzymes catalyzing the sequential steps are taught, one of ordinary skill in the art would have been motivated to carry out the reaction using the enzymes instead of chemically synthesizing SQDG to obtain higher yield and purity.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached on (703) 308-9363. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4534.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak  
Patent Examiner

  
PONNATHAPURACHUTAMURTHY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

November 16, 2001